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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,242	06/24/2003	Ye Fang	SP02-143	1181

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CORNING INCORPORATED
SP-TI-3-1
CORNING, NY 14831

EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,242	FANG ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *3,6-8 and 27-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,9-26 and 42-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 27-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 26, 2005.

2. Claims 3, 6-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 26, 2005.

3. Applicant's election with traverse of claims 1, 2, 4, 5, 9-26, 42-50 in the reply filed on January 26, 2005 is acknowledged. The traversal is on the ground(s) that there would not be a burden of search to search the claims of groups I and II together. This is not found persuasive because of their different classifications. Even should the method of group I be found allowable, further search would be required to determine the patentability of the apparatus of group II. With respect to the traversal regarding the election of species, each of the species is distinct, and would require further search to determine that patentability of the species. For that reason, it would pose an undue burden on examiner to search the claims.

4. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 4, 12, 13, 16-24, 42, 43-46, 47, 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Zweig [US 6,790,632].

With respect to claim 1, Zweig teaches a method comprising providing a reagent comprising a support with a fluid lipid membranes with receptors attached via tethers (claim 18), adding a sample comprising target drug molecules to the reagent (claim 18), and measuring changes in the detectable signal, where the changes indicate the amount of interaction between the target drug molecules and the receptors (claim 18).

7. With respect to claims 2, 4, the membrane can contain carbohydrates (column 11, lines 57-63).

8. With respect to claim 9, the membranes are arranged in distinct microarray spots (column 16, lines 46-59).

9. With respect to claim 12, the monitoring step involves measuring changes in the detectable signal from labels located in the membrane, where the changes indicate the amount of interaction between the target drug molecules and the receptors (claim 18).

10. With respect to claim 13, the label is located with the membranes (claim 18) and is not found with the analyte.

11. With respect to claims 16-17, the support may be glass (column 8, line 1) or porous polymers (column 8, lines 4-8).

12. With respect to claim 18, the supports may be microarray slides (column 19, lines 5-10).

13. With respect to claims 19-20, the slides may be silane treated (column 19, lines 14-16).

14. With respect to claim 21, The biosensor can comprise gold conductive regions (column 18, lines 20-30), with thiol containing biomolecules for coupling (column 15, lines 1-5).

15. With respect to claims 22-24, the silane treated slides are further treated with BSA and activated with N,N'-disuccinimidyl carbonate, to activate the lysine, aspartate, and glutamate residues (column 19, lines 15-20), where are amino groups).

16. With respect to claims 42, 49, Zweig teaches a method comprising providing a reagent comprising a support with a fluid lipid membranes with receptors attached via tethers (claim 18), adding a sample comprising target drug molecules to the reagent (claim 18), and measuring changes in the detectable signal, where the changes indicate the amount of interaction between the target drug molecules and the receptors (claim 18). The membranes are arranged in distinct microarray spots (column 16, lines 46-59).

17. With respect to claims 43, 46, 47, the monitoring step involves measuring changes in the detectable signal from labels located in the membrane, where the changes indicate the amount of interaction between the target drug molecules and the receptors (claim 18).

18. With respect to claim 44, the label provides a fluorescence signal (column 20, lines 50-55).

19. With respect to claim 45, the substrate is washed to remove any leftover material (column 9, lines 60-65).

20. Claims 1, 2, 4-5, 9-12, 14-15, 19-20, 42-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamazaki et al [US 6,699,719].

With respect to claims 1, 42, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines 65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence microscope (column 32, lines 5-10).

21. With respect to claims 2, 4-5, Yamazaki et al teach that the arrayed membranes comprise gangliosides that bind to cholera toxin (column 31, example 8).

22. With respect to claim 9, the arrays are arranged into corrals of 500 microns^2 (column 31, lines 45-50).

23. With respect to claims 10-12, 14-15, 43, 44, the toxin is labeled with Texas Red (column 64-66), the and the fluorescence microscope detects the corrals with bound cholera toxin as red(column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8).

24. With respect to claim 16, the substrate can be a silicon wafer (column 12, lines 20-26).

25. With respect to claim 18, the substrate can comprise well plate having surface detector array devices at the bottom of the wells (column 5, lines 18-20).

26. With respect to claims 19-20, Yamazaki et al teach treating the substrate with a silane (column 18, lines 25-28).

27. With respect to claim 45, the arrays are washed after incubation with the toxin (column 31, line 66 – column 32, line 4).

28. With respect to claim 46, the arrays are incubated with cholera toxin which binds to ganglioside GM1 (column 31, lines 62-65). The fluorescence microscope detects the corrals with bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green

(column 32, lines 5-8). Therefore, a decrease in the green fluorescence indicates binding of cholera toxin to ganglioside GM1.

29. With respect to claims 47-48, Yamazaki et al teach that measurement may be performed using capacitative detection or impedance analysis (column 18, lines 43-46).

30. With respect to claims 49-50, the sample is cholera toxin which binds to ganglioside GM1 (column 31, lines 62-65). The fluorescence microscope detects the corrals with bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8).

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zweig [US 6,790,632] in view of Patton [US 4,993,285].

Zweig teaches a method comprising providing a reagent comprising a support with a fluid lipid membranes with receptors attached via tethers (claim 18), adding a sample comprising target drug molecules to the reagent (claim 18), and measuring changes in the detectable signal, where the changes indicate the amount of interaction between the target drug molecules and the receptors (claim 18). Zweig does not teach treating the surface of the substrate with γ-aminopropylsilane.

Patton, however, teaches that γ-aminopropylsilane is one of several molecules that can be used to treat a substrate in order to obtain an appropriate reactive moiety (column 5, lines 5-25).

Therefore, it would have an obvious in the method of Zweig for the array to have been treated with γ-aminopropylsilane, as suggested by Patton, in order to obtain an appropriate reactive moiety.

33. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al [US 6,699,719] in view of Patton et al [US 4,993,285].

Yamazaki et al teach a method comprising providing et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Yamazaki et al do not teach treating the surface of the substrate with a polylysine, polyethyleneimine, or chitosan.

Patton, however, teaches that γ-aminopropylsilane is one of several molecules that can be used to treat a substrate in order to obtain an appropriate reactive moiety (column 5, lines 5-25).

Therefore, it would have an obvious in the method of Yamazaki et al, for the array to have been treated with γ-aminopropylsilane, as suggested by Patton, in order to obtain an appropriate reactive moiety.

34. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zweig [US 6,790,632] in view of Ness et al [US 6,150,103].

Zweig teaches a method comprising providing a reagent comprising a support with a fluid lipid membranes with receptors attached via tethers (claim 18), adding a sample comprising

target drug molecules to the reagent (claim 18), and measuring changes in the detectable signal, where the changes indicate the amount of interaction between the target drug molecules and the receptors (claim 18). Zweig does not teach treating the surface of the substrate with a polylysine, polyethyleneimine, or chitosan.

Ness et al, however, do teach a surface at least partially covered with a layer of polyethylenimine (PEI) (column 2, lines 40-50). Ness et al further teach that PEI has been extensively used in the art for binding biomolecules, and is effective in this capacity due to its hydrophilicity, and the fact that PEI contains many amino groups which can form salts with acidic groups in a biomolecule (column 5, lines 18-32).

Therefore, it would have been obvious in the method of Zweig for the support to have a layer of PEI, as suggested by Ness et al, for its effectiveness in binding biomolecules due to its hydrophilicity, and the fact that PEI contains many amino groups.

35. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al.[US 6,699,719] in view of Ness et al [US 6,150,103].

Yamazaki et al teach a method comprising providing et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Yamazaki et al does not teach treating the surface of the substrate with a polylysine, polyethyleneimine, or chitosan.

Ness et al, however, do teach a surface at least partially covered with a layer of polyethylenimine (PEI) (column 2, lines 40-50). Ness et al further teach that PEI has been extensively used in the art for binding biomolecules, and is effective in this capacity due to its

hydrophilicity, and the fact that PEI contains many amino groups which can form salts with acidic groups in a biomolecule (column 5, lines 18-32).

Therefore, it would have been obvious in the method of Yamazaki et al for the support to have a layer of PEI, as suggested by Ness et al, for its effectiveness in binding biomolecules due to its hydrophilicity, and the fact that PEI contains many amino groups.

Conclusion

36. No claims are allowed.

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/04/05